K052288

mennenmedical
The Professional's Choice

DEC 2 0 2005

Date: November 10, 2005

Topic: **510(k) Safety and Effectiveness Summary as per 21 CFR Section 807.92(c)**

Special 510(k): Device Modification – VitaLogik

Establishment Name, Registration Number and Address:

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To: Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville MD, 20850

Attn.: Document Control Clerk
From: Micha Oestereich, Regulatory Affairs

Product Name
Proprietary: VitaLogik
Common: Physiological Patient Monitor
Mennen Medical Part Number: 641-000-000

FDA Classification

Classification Name:	Arrhythmia Detector and Alarm
Classification Number:	21 CFR 870.1025
Classification:	Class III
Product Code:	74 DSI

Performance Standards: None promulgated

Voluntary Standards:

***IEC 60601-1:** Medical Electrical Equipment Part:1 General Requirements for Safety File 4745C 1998:12

***IEC 60601-1-1** (2001) Medical Electrical Equipment Part 1-1: General Requirements for Safety Collateral Standard: Safety Requirements for Medical Electrical Systems

***IEC 60601-1-2** (2001): Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.

***IEC 60602-2-27** (1994):
Medical electrical equipment, Part 2,
Requirements for safety of electrocardiograph monitoring equipment.

***IEC 60601-2-30** (1995):
Medical electrical equipment, Part 2 - requirements for safety of automatic cycling indirect blood pressure monitoring equipment

***IEC 60601-2-34** (1994):
Medical electrical equipment, Part 2 - Particular requirements for the safety of direct blood pressure monitoring equipment

* **IEC 60601-2-49** (2001):
Particular Requirements for the safety of multifunction patient monitoring equipment

* **IEC 60601-1-8** (2003):

General requirements for safety-collateral requirements, test & guidance for alarm system in medical electrical equipment & medical electrical systems

Terminology:
Envoy Patient Monitor = the predicate device. The Envoy was cleared for marketing by the FDA in the following 510(k) submittals:

- K974510 – 14th April 1998
- K983864 – 8th October 1999
- K000563 – 17th May 2000
- K001120 – 8th May2001
- K011784 – 16th August 2001
- K022168 – 1st August 2002

VitaLogik = Subject of this Special 510(k). The VitaLogik is a modified device to the Envoy Patient Monitor

1. Device Description: VitaLogik Monitor

The VitaLogik is a configured multi-parameter physiological patient monitor, based on the hardware and software of the Mennen Medical Envoy monitor, without the module rack and modules.

The front end electronic is composing the modules hardware and software into the chassis of the Bed Side Computer =BSC. The input connectors are incorporated in the front panel of the BSC

It is offered in two basic options: Non-Invasive monitor and Full monitor.

In the Non-Invasive version the vital signs are ECG, NIBP, SpO2 and Temperature. The Full monitor includes also two invasive Blood Pressures and Cardiac Output. Both have EtCO2 as an option.

Functional Description of the VitaLogik

The VitaLogik is a configured (no modules) monitor, based on the Envoy monitor, hardware and software, without the module rack and modules.

It measures vital signs such as ECG/Heart rate, NIBP, SpO2, Temperature Cardiac output and EtCO2 as an option.

It will be offered in two basic options: Non-Invasive monitor ECG/Heart rate, NIBP, SpO2, Temperature and Full monitor that includes also two invasive BP and Cardiac output. Both will have EtCO2 as an option.

It will have one serial input for vendor devices.

The VitaLogik uses identical display and patient data as does the Envoy. The Ensemble central station and the Enguard remote monitor can both view the VitaLogik as well as the Envoy.

The VitaLogik has serial input for interface with other vendor devices in the same way that does the UIM module of the Envoy.

Non Invasive VitaLogik version: Vital signs parameters

- Diagnostic 7 or 12 Lead ECG
- Non-invasive Blood Pressure
- Pulse Oximetry (SpO2)
- Temperature
- EtCO2 (optional)

Full VitaLogik version: Vital signs parameters

- Diagnostic 7 or 12 Lead ECG
- Non-invasive Blood Pressure
- Pulse Oximetry (SpO2)
- Temperature
- 2 Invasive Blood Pressure channels
- Cardiac Output
- EtCO2 (optional)

VitaLogik Options:

- Non Invasive monitor
- Full monitor
- EtCO2

Main components of the VitaLogik:
The VitaLogik system consists of:

(A) a **Bed side computer** and
(B) a **Display**

(A) The **Bed side computer** acquires, processes, and converts vital signs from the patient into waveforms and digital signals.

The VitaLogik can acquire the following physiological signals of the patient:

- ECG – Waveform and measures Heart Rate, ST and Arrhythmia
- Blood Pressure – Waveform and measures Systole, Diastole and Mean Pressure
- Temperature – As a numeric value in C^{o} or F^{o}
- SpO2 – Photoplethysmographic waveform and numeric value of the oxygen saturation and pulse rate

- NIBP – Systolic, Diastolic and Mean pressure with measuring time stamp
- EtCO2 – EtCO2, inCO2 and Respiration Rate

(B) The **Display** is used to display the measurement and waveforms, and alarms. It does not have any control function.

INDICATIONS FOR USE

VitaLogik is intended for use as a multiparameter physiological patient monitoring system.

The VitaLogik can monitor ECG/heart rate, two invasive blood pressure channels, two temperature channels, pulse oximetry, respiration, non-invasive blood pressure and EtCO2. This effectively allows the VitaLogik to monitor a wide-range of adult, pediatric and neonatal patient conditions, in many different areas of the hospital.

Functions include display of multiparameter waveforms, vital signs, alarm & status messages.

The Mennen Medical VitaLogik is intended for sale as a system for monitoring and recording patient information or any in-hospital application requiring patient monitoring.

The following are examples of intended clinical applications:

- Critical Care Patients
- Cardiac Step-down/Telemetry Units
- Emergency Departments
- Intra-operative (Anesthesia) Monitoring
- Post Anesthesia Care

2. Substantial Equivalence: VitaLogik versus Envoy

Comparison: Envoy with VitaLogik

The following tables summarize and compare data on the Envoy (predicate device –K001120) to the subject of this Special 510(k) submittal, the VitaLogik.

	Envoy	VitaLogik
Part/Option Number	550-010-017	641-000-000
Input Circuit Parameters		
Chassis Leakage Current	All patient signal inputs fully isolated (<50 µA) Meets or exceeds ANSI standard: "Safe Current Limits for Electromedical Aparatus," (SCLE) Dec, 1978 item 2.1.1.	Same
Degree of protection against electrical shock	Type CF and BF. ECG, IBP and CO = CF NIBP and SpO2 = BF	Same
Electrosurgical Interference Suppression	Yes	Same
ECG	**3/5/6/12 Lead**	Same
Input Impedance:	Typical 20 MΩ Minimum greater than: 5 MΩ differential, DC to 10 Hz; 2.5 MΩ differential 10 to 100 Hz 3 MΩ differential at 10 Hz	Same
Input Dynamic Range:	±5mV p-p at a rate up to 320mV/sec, as per ANSI/AAMI EC13 [8] Para. 3.2.9.1.	Same

	Envoy	VitaLogik
Input offset	± 300mV, as per ANSI/AAMI EC13 Para. 3.2.9.1.	Same
Noise:	Less than 30 μ V p-p referenced to input	Same
Defibrillator Protection:	Up to 5 KV. Amplifier Recovery time: < 3 seconds	Same
Gain:	Manual selection of 1/4, 1/2, 1, 2, 4, 8 mV/cm	Same
ECG Analog Output:	1 Volt / mVolt	Same
Sampling Rate and Resolution	Sampling rate: 640Hz Resolution: 22 bit	Same Same
Frequency Response	Diagnostic : 0.05 to150 Hz Monitoring: 0.5 to 40 Hz Exercise: 1.0 to 25 Hz ST: 0.05 to 40 Hz	Same
QRS Detection Range	Height: 0.25 to 5.0 millivolt Width: 70 to 120 mSec	Same
Heart Rate Counting	Range: 20 to 300 BPM Accuracy: ± 2 BPM Note: Values below 20 are forced to zero.	Same
Heart Rate Alarm Settings	High and low rate: 20 - 250 BPM non-overlapping	Same
Leads analyzed for Heart Rate and Arrhythmia Configuration	Top two displayed	Same

	Envoy	VitaLogik
ECG Leads: 3 Lead cable 5 Lead cable 6 Lead cable 12 Lead module	 -- I or II or III -- I, II, III, aVR, aVL, aVF, V -- I, II, III, aVR, aVL, aVF, Va, Vb -- I, II, III, aVR, aVL, aVF, V1-V6	Same
Common Mode Rejection	120 dB, minimum	Same
Lead Fault Detection	Based on impedance	Same
Pacemaker Detection and Rejection	Amplitude: 2 mV to 700 mV Width: 0.1 ms to 2.0 ms Pacemaker flag inserted into displayed waveform	Same
Data Storage :	• Beat notification • RR Interval • Heart Rate • ST values • Arrhythmia • Alarms • Parameter settings • Cycle time and measurement time markers • All measurements for 36 hrs • S/D/M and pulse rate values • Alarm event markers	Same
Respiration		
Lead Selection	RA-LA or RA-LL	Same
Respiration Sensitivity Range	0.2 ohm to 5.0 ohm	Same

	Envoy	VitaLogik
Impedance Range	100 to 3,000 ohm @ 65 kHz	Same
Respiration Rate Counting Range	8 to 150 BPM	Same
Respiration Frequency Response	0.13 to 2.5 Hz (-3 dB)	Same
Sampling rate:	38 Hz	Same
Respiration Alarm Settings	Low rate: 0 - 150 BPM High rate: 8 - 150 BPM Apnea: User configurable Cardiac coincidence alarm	Same
Data Storage :	• Respiration rate • Respiration rate Alarms • Apnea alarms • Waveform labels and annotations • Instantaneous resp. rate • Alarm event markers	Same
BP	LED for function indication	Same
Transducer Excitation Voltage	+5 VDC Separate excitation driver for each channel	Same
Site Labels:	BPX, ART, PAP, CVP, RAP, LAP, ICP	Same
Input Sensitivity	5 microVolt/Volt/mmHg	Same
Dynamic Range	-- Pressure range: -50 to +300 mmHg -- Zero range: ±200 mmHg -- Total dynamic range: -200 to +450 mmHg	Same

	Envoy	VitaLogik
Zero Accuracy	±0.2 mmHg	Same
Zero Drift	Less than ±0.2 mmHg in 24 hours, at constant temperature)	Same
Blood Pressure Accuracy	±2 mmHg or ±2%, whichever is greater, exclusive of transducer	Same
Blood Pressure Linearity	within 1% across entire range	Same
Waveform Frequency Response	0 - 15 Hz	Same
Sampling Rate	320 Hz	Same
Fault Detection	• Shorted transducer • Transducer in/out • Cable out	
Data Storage	Systolic, Diastolic and Mean Alarms	Same
Cardiac Output and Temperature		
Adapter and Compatibility Cables	-- COSet[a] Interface cable -- Ice Bath Cardiac Output interface cable -- Dual temperature interface cable (ysi-400)	Same
Temperature Range	Blood temperature: 27°C to 45°C (80.6° to 113° F) Injectate temperature: 0°C to 25°C (32° to 77° F) Body temperature: 0°C to 43°C (32° to 109.4°F)	Same

	Envoy	VitaLogik
Accuracy	Blood temperature: ±0.1°C (32.18°F) Injectate temperature: ±0.1°C (32.18°F)	Same
Excitation	10μA, maximum	Same
Frequency Response	0 to 15 Hz	Same
Cardiac Output Determination Range	0 to 20 liters per minute	Same
Injectate Volumes	1, 3, 5, and 10cc	Same
Computation Constants	Table built as new values are used	Same
Displayed Data	• Cardiac Output, • Cardiac Index, • Stroke Volume, • Stroke Volume Index, • Blood Temperature, • Injectate Temperature, • Trial Number	Same
Data Storage : **– In Cardiac Output mode**	• Cardiac Output • Hemodynamic Calculation results • Measuring time	Same
Data Storage **– In Two Temp mode:**	• Temperatures • Delta-Temp • Temperature Alarms	Same
Non-Invasive Blood Pressure	LED for function indication Oscillometric Method	Same
Displayed Parameters	Systolic, Diastolic, Mean pressure values Time of last measurement, measurement Interval,	Same

	Envoy	VitaLogik
Inflation Rate	Within 5 sec.	Same
Initial Inflation:	150 mmHg (adult) 120 mmHg (pediatric).	Same
Cycle Times	Deflation time (typical): 30 sec. BP time-out: 60 - 180 sec	Same
Measurement Ranges, Adult (in mmHg)	Systolic: 25 to 255 Diastolic: 10 to 220 Mean: 18 to 235	Same
Measurement Ranges, Neonatal (in mmHg)	Systolic: 20 to 135 Diastolic: 5 to 110 Mean: 10-125	Same
Modes:	Auto, Manual, STAT	Same
Pressure (Transducer) Accuracy	±3 mmHg or ±2%, whichever is greater	Same
Heart Rate	40 to 140 BPM	Same
Data Storage :	• measurement time markers • S/D/M • Alarm event markers	
Pulse Oximetry (Sp02)	Masimo or Nelcor Technology	Same
Saturation Range	1% to 100% Sp02	Same
Sp02 Accuracy	% SpO2 ± 1 standard deviation	Same
Pulse Rate Range	20 to 250 BPM ±3 BPM	Same
Saturation alarm limits:	50% to 100%	Same
Data Storage :	• Heart rate and O2 Sat • Alarms	Same

	Envoy	VitaLogik
End Tidal CO2 Microstream	LED for function indication Air outlet	Same
Displayed Data	Waveform labels and annotations EtCO2, inCO2 and respiration rate values	Same
CO2 Display Range:	0-100 mmHg	Same
Typical Accuracy: CO2	±2 mmHg for CO2 range of 0-38 mmHg ±5% for CO2 range of 39-99 mmHg + 0.08% for every 1 mmHg above 38 mmHg	Same
Typical Accuracy: **Respiration Rate**	0 – 70 bpm +/- 1 bpm 71 – 120 bpm +/- 2 bpm 121 – 150 bpm +/- 3 bpm	Same
Rise Time	190 msec (10% - 90%)	Same
Delay Time	2.7 Sec (10% - 90%) typical	Same
CO2 Alarm Limits:	0 to 100 mmHg/ 0 to 10% 0-15 kPA	Same
Accuracy:	for % measurement: 0.1% for mmHg measurement: 1mm	Same
Respiration Rate Alarm Limits:	Neonatal: 0 to 150 BMP Adult: 0-50 BPM	Same
Sidestream Flow Rate:	50 ml/min. nominal	Same
Start-up Time:	30 sec. typical	Same
Automatic Compensation:	At least once per hour	Same
Ambient Temperature:	0-65° C Sidestream	Same

	Envoy	VitaLogik
Humidity:	10-95% RH, non-condensing	Same
Barometric Pressure:	430-795 Hg (-1250 to 15,000 ft.)	Same
Data Storage :	• EtCO2, inCO2 and Respiration Rate values • Alarms • Apnea Alarm	Same
Universal Input	Interface to other vendor device protocols in RS232.	Same
Number of inputs	One on Uniport module Three on Multiport	One only
Cable In/Out Detection	Yes	Yes
Provides **electrical isolation** between the monitor and external device/s	Yes	Yes
Displays clinical and technical alarms from external device/s	Yes	Yes
Clinical Software Features		
Waveform Display	• 175 mm horizontal area • 7 sec. @ 25mm/sec • Up to 8 traces • Overlapping traces • Expanded display	Same
Numeric Display	85 mm horizontal area • 25mm Heart Rate • 20mm Sp02 • "Big Numbers"	Same

	Envoy	VitaLogik
Default Alarms	• User defined • Fixed or calculated values	Same
Data Display	• Tabular charts • Graphic trends	Same
Electrical Specifications		
Main Processing Unit	AC Power Input 90-132/180-264 VAC, single phase, at 47-63 Hz. Maximum current: Dual fuse: each 3.15A, 250V. Slow Blow	Same
AC Power Output for Local Display	90-132/180-264 VAC at 47-63 Hz, single phase. Comes through the MPU power switch. Maximum Output power: 130W	Same
Display Monitor	15", 17", 20" and flat screen (15", 18") are available. Complies with Part 15 of the FCC Rules	Same
Environmental Spec.		

	Envoy	VitaLogik
Operating Conditions	Temperature: +5°C to +40°C Humidity: 10 to 95 percent, non-condensing Altitude: -350 to 3050 meters (-1300 to 10,000 feet) Vibration/Shock: per Mennen Medical: Design for Regulatory	Same
Storage Conditions	Temperature:-15 °C to +60 °C Humidity: 10 to 95 percent, non-condensing Altitude: -350 to 5000 meters (-1300 to 17,000 feet)	Same

	Envoy	VitaLogik
Displayed Waveforms		
ECG	Up to 12 lead	Same
BP	Up to 4, separate or superimposed	2 separate or superimposed
Respiration	1	Same
SpO2	1	Same
EtCO2	1	same
Displayed Numeric Parameters		
Heart Rate	Yes	Same
Respiration Rate	Yes	Same
SpO2	Yes	Same

	Envoy	**VitaLogik**
Displayed Waveforms		
ECG	Up to 12 lead	Same
BP	Up to 4, separate or superimposed	2 separate or superimposed
Respiration	1	Same
SpO2	1	Same
EtCO2	1	same
Displayed Numeric Parameters		
BP – Systolic, Diastolic, Mean	Yes	Same
Temperature	2	Same
EtCO2	Yes (optional module)	Optional
Alarm Indications	Yes	Same
Display Functions	**Envoy**	**VitaLogik**
Change ECG Lead Selection	YES	Same
Display of Arrhythmia Information	YES	Same
Data Review: Trends - Graphic	YES	Same
Data Review: Chart – Tabular	YES	Same
User defined Configuration Setup	YES	Same
User defined Default Settings	YES	Same
Accessories	Envoy accessories	Same
GUI	Menu driven	same

Comparison

Hardware comparison

Item	Envoy	VitaLogik
Front End electronics	Module rack	Integrated front end electronics
Front Panel keys	10	3
Quicknobe	Yes	Same
Main screen	Yes	Same
Escape	Yes	Same
Vital Signs - Orange	Yes	No
Patient data - Orange	Yes	No
Setup - Orange	Yes	No
Timer - Yellow	Yes	No
Print – Green	Yes	No
Record – Green	Yes	No
Event – Green	Yes	Yes
Freeze – Green	Yes	No
Silence – Red	Yes	Yes
Alarm Off – Red	Yes	Yes

Main Menu items comparison

Menu item	Envoy	VitaLogik
Vital Signs	Dynamic list of vital signs per available modules	Fixed list of vital signs
ECG	Yes	Yes
Respiration	Yes	Yes
NIBP	Yes	Yes
Temperature	Yes	Yes
SpO2	Yes	Yes
BP	Yes	Yes
CO	Yes	Yes
EtCO2	Optional	Optional
Spirometry	Yes	No
EEG	Yes	No
Patient data	Same	Same
Setup	Same	Same
Setup -- Software version	Shows software version and module rack, setting.	Show only software version
Setup – Parallel port	Yes	No
System Setup	Same	Same
System Setup– Parallel port setup	Yes	No

3. Similarities and Differences in Design:

VitaLogik versus Envoy

The following technological and other characteristics/features apply to both the VitaLogik and the Envoy.

- Intended for use in hospitals
- Do not change the functionality of the monitor
- Isolated inputs for vital signs sensors
- ECG amplifier front end with defibrillator protection
- Invasive BP input circuit
- Non Invasive BP measurement
- SpO2 measurement
- Selectable filters for ECG
- Analog output for ECG and BP
- Display of vital signs and physiological waveforms
- Same GUI and same menus
- Monitoring at central nurse station

The major differences between the VitaLogik and the Envoy are

- The VitaLogik does not have a module rack
- The VitaLogik is a configured monitor with a fixed set of parameters
- The VitaLogik front panel is different from the Envoy
- The VitaLogik has only 5 hardware keys as compared to 12 on the Envoy panel

The VitaLogik monitor provides access to the functions of the Hardware keys, which were omitted, via the menus. On the original Envoy monitor the Hardware keys were used as a shortcut to the same menu items, thus functionality is not reduced. If one or more of the missing hardware keys in the VitaLogik are frequently used in a given setup the missing hardware key can be replaced by software Quickeys available on both the Envoy and it's modified version VitaLogik.

For example on the Envoy there is a hardware key to 'Patient Data'. On the VitaLogik the 'Patient Data' can be reached via the Main menu, or a software Quicknob can be create as a shortcut to 'Patient Data'.

We submit that the change from Module rack monitor to configured monitor with the same menue and display does not amount to a change in the "fundamental scientific technology" of the Envoy and does not disqualify the VitaLogik from being the subject of a Special 510(k).

The example brought down in 21 CFR 862.9 of a change in the "fundamental

scientific technology" ("a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade"), involves a radical change in the method and type of treatment given to the patient.

The VitaLogik SW is a brunch of the Envoy SW that takes into account the replacement of the module rack and modules into a configured monitor

The following table compares the major software element and/or changes done in the VitaLogik vs. the Envoy:

SW Component	Envoy	VitaLogik
Display	All waveforms and numeric vital sings	Same
Operating System	QNX4	Same
GUI	Same	Same
Menus	Full set	Same
Vital signs	Depend on available modules	Fixed

Conclusion of comparison of technological characteristics:
We consider the VitaLogik monitor to be substantially equivalent to the Envoy monitor and we submit that any differences between the two systems

- fall within the scope of a Special 510(k) Device Modification and
- do not raise any new issues of safety and effectiveness

Testing

The VitaLogik has been subject to extensive safety and performance testing. Final testing for the system included various performance tests designed to ensure that the device meets all functional requirements and performance specifications. Safety testing and EMC testing were performed by an independent testing laboratory to ensure that the device complies with applicable industry and safety standards.

Indications for Use

The Indications for Use of the VitaLogik remains basically the same at those set out for the Envoy (predicate device), K001120. See page 16 below for the Indications for Use.

INDICATIONS FOR USE

VitaLogik is intended for use as a multiparameter physiological patient monitoring system.

The VitaLogik can monitor ECG/heart rate, two invasive blood pressure channels, two temperature channels, pulse oximetry, respiration, non-invasive blood pressure and EtCO2. This effectively allows the VitaLogik to monitor a wide-range of adult, pediatric and neonatal patient conditions, in many different areas of the hospital.

Functions include display of multiparameter waveforms, vital signs, alarm & status messages.

The Mennen Medical VitaLogik is intended for sale as a system for monitoring and recording patient information or any in-hospital application requiring patient monitoring.

The following are examples of intended clinical applications:

- Critical Care Patients
- Cardiac Step-down/Telemetry Units
- Emergency Departments
- Intra-operative (Anesthesia) Monitoring
- Post Anesthesia Care

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2005

Mennen Medical, Ltd
c/o Ms. Micha Oestereich
QA & Regulatory Affairs Manager
P.O. Box 102
Rehovot, 76100
ISRAEL

Re: K052288
Trade Name: VitaLogik
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (including ST-segment measurement and alarm)
Regulatory Class: Class III (three)
Product Code: DSI
Dated: November 16, 2005
Received: November 22, 2005

Dear Ms. Oestereich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052288

Device Name: VitaLogik

Indications For Use:

VitaLogik is intended for use as a multiparameter physiological patient monitoring system.

The VitaLogik can monitor ECG/heart rate, two invasive blood pressure channels, two temperature channels, pulse oximetry, respiration, non-invasive blood pressure and EtC02. This effectively allows the VitaLogik to monitor a wide-range of adult, pediatric and neonatal patient conditions, in many different areas of the hospital.

Functions include display of multiparameter waveforms, vital signs, alarm & status messages.

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The following are examples of intended clinical applications:

- Critical Care Patients
- Cardiac Step-down/Telemetry Units
- Emergency Departments
- Intra-operative (Anesthesia) Monitoring
- Post Anesthesia Care

Prescription Use x AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Zimmerman

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K052288